

FDA Update: New pediatric information available for 52 products

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Food and Drug Administration's Office of Pediatric Therapeutics and the Division of Pediatric & Maternal Health

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In 2015, new pediatric information was added to labeling of 43 drugs, two vaccines and seven blood products. The spectrum of approved agents to treat pediatric patients continues to expand (see table).

The new pediatric labeling includes the following conditions:

- opiate overdose,
- pain,
- migraines,
- nausea and vomiting,
- attention-deficit/hyperactivity disorder,
- asthma,
- anemia,
- seizures,
- ulcerative colitis,
- hemophilia A and
- a therapeutic vaccine.

The seven drugs for which studies did *not* establish the effectiveness for use in children include Velcade for relapsed acute lymphoblastic leukemia and lymphoblastic lymphoma; Tarceva for recurrent or refractory ependymoma; Asacol for maintenance of remission of ulcerative colitis; Lamictal for maintenance treatment of bipolar disorder; Xopenex HFA Inhalation Aerosol and Xopenex Inhalation Solution for asthma or reactive airway disease; and Saphris for adjunctive therapy in the treatment of bipolar I disorder.

In addition, important safety information was added to the labeling of four products. For example, information on pediatric depression was added to the Warnings section for Edurant, which is used to treat HIV.

Examples of products with pediatric labeling changes

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Drugs		
Emend Oral Suspension (aprepitant)	Prevention of chemotherapy-induced nausea and vomiting in patients ages 6 months of age and older	December 2015

QuilliChew ER extended-release chewable tablets (methylphenidate hydrochloride)	Attention-deficit/hyperactivity disorder in pediatric patients 6-17 years	December 2015
Nucala (mepolizumab)	Treatment of severe asthma in patients 12 years and older with an eosinophilic phenotype	November 2015
Caldolor Injection (ibuprofen)	Management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever in pediatric patients 6 months and older	November 2015
Narcan Nasal Spray (naloxone hydrochloride)	Emergency treatment of known or suspected opioid overdose in adults and pediatric patients of all ages	November 2015
Delzicol (mesalamine)	Treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older	September 2015
Aranesp (darbepoetin alfa)	Initial correction of anemias in pediatric patients	July 2015
Fycompa (perampanel)	Treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older	June 2015
Treximet (sumatriptan/naproxen)	Acute treatment of migraine with or without aura in pediatric patients 12-17 years	May 2015
ProAir RespiClick (albuterol sulfate)	Treatment or prevention of bronchospasm and prevention of exercise-induced bronchospasm in pediatric patients 12-17 years	March 2015
Blood products		
Adynovate (Antihemophilic Factor [Recombinant], PEGylated)	Adult and adolescent patients (12 years and older) with hemophilia A (congenital factor VIII deficiency) for 1) on-demand treatment and control of bleeding episodes and 2) routine prophylaxis to reduce the frequency of bleeding episodes	November 2015
Vaccines		
Bexsero (Meningococcal Group B Vaccine)	Active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B in patients 10 through 25 years of age	January 2015

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